

United States Department of Agriculture Animal and Plant Health Inspection Service Plant Protection & Quarantine 4700 River Road Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil

Importation

Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:Dr. Frisby SmithPERMIT NUMBER: P526P-19-02634ORGANIZATION:Bayer CropScience - BiologicsAPPLICATION
NUMBER:P526-190522-077

ADDRESS: 890 Embarcadero Drive FACILITY 3279
West Sacramento, CA 95605 NUMBER:

MAILING ADDRESS: 890 Embarcadero Drive HAND CARRY: No

West Sacramento, CA 95605

DATE ISSUED: 06/11/2019

PHONE: 916-661-3322

FAX: EXPIRES: 06/11/2022

DESTINATION: 890 Embarcadero Drive, West Sacramento, CA 95605
DESIGNATED CA, El Segundo; CA, South San Francisco; FL, Miami
(Cargo, DHL, Fed Ex, UPS, etc.); GA, Atlanta; NJ,
Linden; NY, Jamaica; TX, Humble; WA, SeaTac

Under the conditions specified, this permit authorizes the following:					
Regulated Article	Life Stage(s)	<u>Intended Use</u>	Shipment Origins	Originally Collected	Culture Designation
Beauveria bassiana	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	P-BLX Bb01 to Bb10
Beauveria spp.	Mycelia, Petri dishes/culture tubes, Spores	Research - Growth Chamber (lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	P-BLX Bsp01 to Bsp10
Candida guilliermondii	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	2H13 - anamorph
Clonostachys rosea	Lyophilized plant or microbes, Microbial solutions, Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Within the Continental U.S.	BVT-CR7 (origin US)

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Clonostachys rosea	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	88-710, PR1170
Clonostachys rosea	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North	Originally Collected from Foreign and Domestic Locations	IK 726 (origin Denmark)
Clonostachys rosea	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	ACM941+C-Wet, PR1132
Clonostachys rosea	dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	Prestop, J1446 (origin Finland)
Coniothyrium minitans	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	Con.m 14, Con.m 15 (origin Germany)
Coniothyrium minitans Con m 91-08 (EPA Reg)	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	Con m 91-08, DSM 9660 (origin Germany)
Gliocladium catenulatum strain J1446 (EPA reg)	Lyophilized plant or microbes, Microbial solutions, Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany,	Originally Collected from Foreign Locations	Prestop, J1446 (origin Finland)
Isaria fumosorosea	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	IFPC200613 (origin Columbia)
Isaria fumosorosea	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and	Isa.f. 14, Isa.f. 15 (origin Germany)
Isaria fumosorosea (Apopka Strain 97 EPA reg.)	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North	Originally Collected from Foreign and Domestic Locations	Apopka 97 (origin United States)

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Carl Schulze	06/11/2019



Isaria spp.	Mycelia, Petri dishes/culture tubes, Spores	Research - Growth Chamber (lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	I-12014, DSM 29396 (origin Germany)
Lecanicillium lecani	i Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North	Originally Collected from Foreign and	HRO Lec. 12 (origin Germany)
Metarhizium anisopliae	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North	Originally Collected from Foreign and Domestic Locations	P-BLX Ma01 to Ma10
Metarhizium anisopliae F52 (EPA reg)	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany,	Originally Collected from Foreign and Domestic Locations	P-BLX MA F52
Meyerozyma guilliermondii	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	2H13 - teleomorph
Paecilomyces lilacinus	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	PL251a, PL251b, PL251c, PL251d (origin Germany)
Paecilomyces lilacinus strain 251(EPA reg)	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany,	Originally Collected from Foreign and Domestic Locations	PL 251, DSM 23289 (origin Philippines)
Penicillium bilaii	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and	Pb 001, ATCC 20851 (origin Canada)
Penicillium frequentans	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	PF909, ATCC-66108
Purpureocillium lilacinum	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany,	Originally Collected from Foreign and Domestic Locations	

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Talaromyces flavus	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	VII 7b, DSM 27246 (origin Germany)
Trichoderma asperellum	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	B 35 (origin Poland)
Trichoderma atroviride	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	T 1 (origin France)
Trichoderma harzianum	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	Eco T (origin South Africa)
Trichoderma harzianum	Lyophilized plant or microbes, Microbial solutions, Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign Locations	ESP1, ESP4, ESP5, ESP9 (origin Spain)
Trichoderma saturnisporum	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	PBP-TH-001 (origin Germany)
Trichoderma virens	Mycelia, Petri dishes/culture tubes, Spores	Research - Greenhouse (growth chamber and lab included)	Canada, Germany, Europe, North America (except USA)	Originally Collected from Foreign and Domestic Locations	GL21, GL21a, GL21b, GL21c (origin United States)

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

DHS CBP INSPECTORS - SHIPMENT BY BONDED CARRIER

- 1) Confirm that the carrier of the shipment imported under this USDA PPQ 526 permit is commercially bonded.
- 2) Confirm that the imported shipment has a valid USDA PPQ Form 599 Red/White label attached to the exterior for routing to a USDA APHIS PPQ Inspection Station or other "Designated Port" as stated on the Permit. A valid label will have the permit number, expiration date, label number, and address of a USDA APHIS PPQ Plant Inspection Station/Designated Port. PLEASE NOTE: In the event of a shipment of bulk container with discrete units, a single PPQ Form 599 Red/White label may be used.
- 3) Validate the permit in ePermits using the CBP search feature.
- 4) If a valid PPQ Form 599 Red/White label is not attached to the exterior of the package or the label has been covered or is otherwise not legible, then forward to the nearest USDA APHIS PPQ Plant

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Inspection Station.

5) If the address on the airway bill does not match the address on the PPQ Form 599 Red/White label then forward the package to the nearest USDA APHIS PPQ Plant Inspection Station/designated port shown on the PPQ Form 599 label. All costs associated with rerouting misaddressed packages will be assumed by the permit holder.

APHIS PPQ INSPECTORS at PIS - High-Risk Microbial

Follow the instructions in the Plant Inspection Station Manual for High-Risk Microbial, Unknown Organisms (Diagnostics) Red and White Labeled Packages (must be opened in a biosafety cabinet; see procedures for handling on page 3-7-40). For questions or concerns, contact the USDA APHIS PPQ Pest Permit Branch in Riverdale, MD, at 301-851-2046, toll free 866-524-5421.

PERMIT GUIDANCE

- 1) Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury; please refer to https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx
- 2) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.
- 3) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import export/animals/animal import/animal imports an approducts.sh tml
- 4) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at http://www.cdc.gov/od/eaipp/
- 5) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 6) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

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USDA-APHIS issues this permit to Frisby Smith with Bayer CropScience - Biologics in West Sacramento, California. This permit authorizes the importation of pure cultures of the listed organisms from Canada, Germany and/or Europe to California.

This permit also authorizes the use of the regulated organisms for laboratory, greenhouse, and growth chamber research in the listed APHIS approved facility #3279. The permit further authorizes the continued curation of the listed organisms received under prior permit(s) in the listed APHIS approved facility #3279.

Plant inoculations using organisms that are listed only to the genus level (Beauveria spp. and Isaria spp.) are restricted to the laboratory and growth chambers. Plant inoculations using organisms that are listed to the species level are authorized in the laboratory, growth chambers, and greenhouse.

- 1. This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
 - The permit number or a copy of the permit must accompany the shipment.
 - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
 - You are legally responsible for complying with all permit requirements and permit conditions.
 - The regulated material and shipping container(s) are subject to inspection by officials of Custom and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for expenses.
 - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
 - Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.



2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.
- Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.
- 3. This permit does not authorize movement or use of organisms listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. For a complete list of Select Agents please visit:



https://www.selectagents.gov/selectagentsandtoxinslist.html

Select agents include: Peronosclerospora philippinensis (Peronosclerospora sacchari), Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia solanacearum, Rathayibacter toxicus, Sclerophthora rayssiae, Synchytrium endobioticum, Xanthomonas oryzae, Bacillus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Burkholderia mallei, and Burkholderia pseudomallei.

4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to adhere to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

- 5. Samples of infected plant material must be bare-root or washed free of soil prior to shipment to the permit holder.
- 6. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
- 7. After PPQ issues this 526 permit, you will need to request Red/White labels (PPQ Form 599) at least 5 days in advance of your shipping date. If you applied for your permit online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to Redandwhitelabelrequest@usda.gov. All email requests must come from the permit holder or designee. If requested by the designee, the permit holder must be copied on all requests. Specify the approved port as listed on the permit and the total number of labels needed. You may request additional labels the same way.

Packages without labels on the exterior may be refused entry.

Review label instructions at: https://www.aphis.usda.gov/planthealth/shipping-red-white-labels

You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.



- 8. This permit does not authorize hand carrying (baggage, personal belongings, auto, etc.). Any organisms imported by these methods will be seized and destroyed.
- 9. Upon receipt, all packages must be opened within a Class II or III biosafety cabinet in the approved containment facility identified above to prevent the potential dissemination of the package contents. Cultures must be in a sealed container during transport to or within the permit holder's assigned research facilities.
- 10. All research activities, plant inoculations and subsequent disease development must occur within the APHIS approved Containment Facility identified above that has been inspected and found adequate for containment of the organisms received under this permit. Access to this facility must be restricted to authorized personnel.
- 11. Plant inoculations using organisms that are listed on this permit at the species level are authorized in greenhouses and growth chambers. Plant inoculations using organisms listed on this permit at the genus level or higher are restricted to growth chambers only.
- 12. Standard Operating Procedures (SOPs) must be filed with, and approved by, the APHIS PPQ Pest Permit Staff at: email: pest.permits@usda.gov; phone: 866-524-5421; fax: 301-734-8700; address: 4700 River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, permit conditions take precedence. APHIS PPQ must approve any changes to the SOPs before implementation.

A list of all persons with access to the containment facility must be maintained and available upon request by Federal or State Regulatory Officials.

All persons working with the regulated material/organism(s) must be trained on, and implement the permit conditions, and all APHIS approved SOPs governing the facility listed above.

- 13. Runoff water from inoculated plants must be collected and sufficiently treated by heat (heated for 140C for three minutes) or chemical means, and be handled in such a way as to prevent movement of the live regulated organisms into adjacent agricultural or environmental areas as per the Standard Operating Procedures (SOPs) filed with, and approved by, the APHIS PPQ Pest Permit Staff.
- 14. At the conclusion of all experiments infested soil, infested growing media and infected/infested plant materials must be treated by heat (steam sterilized for 2 hours at 100C) or chemical means sufficient to kill or destroy all plant pest life stages prior to disposal as per the Standard Operating Procedures (SOPs) filed with, and approved by, the APHIS PPQ Pest Permit Staff.
- 15. Modifications to the containment facility or any changes that affect the containment of the regulated materials/organisms must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).

	Permit Number P526P-19-02634
THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.	DATE
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Carl Schulze	06/11/2019



- 16. Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, and the date the isolate was received. These records must be made available to Federal and State regulators upon request.
- 17. When not working with the regulated materials/organisms, you must store and/or maintain them within the APHIS approved containment facility identified above. All stored regulated materials/organisms must be kept in a locked area with access limited to authorized personnel.
- 18. DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

Prior to disposal or reuse, you must treat all contaminated and all potentially contaminated materials by one of the following methods, either alone or in combination:

1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes.

Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.



OR

The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

- d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the Geobacillus sterothermophilus and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.
- 19. As an alternative to the DEVITALIZATION AND WASTE DISPOSAL requirements listed above, devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.
- 20. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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